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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1654

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/629,341

Applicant(s)

Lee et al.

Examiner

Christopher Tate

Art Unit

1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

Claims 1-11 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-11 are rendered vague and indefinite by the terms "material" and "materials". These terms appear to be attempting to define the chemical structure shown in claims 1 and 3. However, the term "material" does not adequately define such a chemical structure as typically construed in the chemistry art. Accordingly, the metes and bounds of these terms are not clearly nor adequately delineated - e.g., is the material/materials defining an extract material containing the recited chemical structure? Further, in claim 3, the plural recitation "the materials" is unclear and confusing since only one chemical structure is shown. It is suggested that these two terms be omitted and replaced by the word --compound-- wherever they appear in the claims.

Claims 3-9 are rendered vague and indefinite because they fail to recite a complete process - i.e., they fail to recite a final recovery/isolation step of obtaining the recited (purified) compound (as claimed, the instantly claimed process does not result in a final step of recovering/isolating the purified compound). A final recovery/isolation step of the claimed purified compound is essential in adequately defining such a process (as well as in terms of utility) and to be consistent with the preamble language of claim 3 .

Claim 3 is also rendered vague and indefinite because throughout the claim, plural recitations are used - e.g., "the materials", "extracting antioxidative ingredients", "fractionating the antioxidative ingredients", "purifying the solvent fractions" (please note that this latter phrase does not define which solvent fraction the recited compound is actually contained in), however only one chemical compound is shown in claim 3 (and instantly disclosed), making claim 3 exceedingly vague and indefinite.

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Claim 3 is further rendered vague and indefinite by the phrases "in solvent" and "solvent fractions" (last two lines of claim 3) because it is unclear what solvents are being defined by these broad phrases - e.g., organic solvents or some other non-organic solvent such as carbon dioxide? It is suggested that the term --organic-- be inserted before the word "solvent" in both these phrases.

Claims 6 and 7 are rendered vague and indefinite because in each case, the secondary and tertiary steps fail to adequately define that "an aqueous methanol layer" (e.g., "a secondary solvent-fractionating step of fractionating an aqueous methanol step obtained in the primary step") is, in fact, --the-- aqueous methanol layer obtained in the previous step (e.g., as drafted, this phrase could be defining an aqueous methanol fraction outside the methanol fraction obtained by the defined process of the previous step). Accordingly, it is suggested that the word "an" within these phrases be omitted and replaced with --the--.

Claims 2 (line 1) and 8 (line 2) recites the limitation "the extract". There is insufficient antecedent basis for this limitation in the claims. Claim 8 depends from claim 3 and claim 2 depends from claim 1, neither of which recite an extract, per se.

Claims 10-11 provide for the use of , but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Oishi (US 5,165,933) or Kim et al. (J. Korean Fish. Soc., 1996).

A material (which is interpreted as meaning an extract material) and/or an organic solvent extract obtained from *Ecklonia cava*, and a method of extracting *Ecklonia cava* is apparently claimed.

Oishi teaches a hot water extract and a repeatedly fractionated organic solvent extract material obtained from *Ecklonia cava* which were assayed (purified) via chromatography (see, e.g., abstract, col 1, line 58 - col 2, line 34; Example 1; Example 5).

Kim et al. teach fractionated extract materials obtained from *Ecklonia cava*, including a methanol-soluble fraction thereof, using column chromatography (see entire document).

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Please note that the recited compound (within an extract/extract material) would inherently and necessarily be present within the hot water and fractionated extract preparations taught by Oishi and within the fractionated extract preparations of Kim et al. (including the methanol fraction thereof) because, as readily admitted by applicants, the recited chemical compound is extractable using water as well as various other organic solvents such as ethanol and methanol (see, e.g., paragraph bridging pages 7-8 of the instant specification).

Therefore, each of the cited references is deemed to anticipate the instant claims above, as drafted.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (Nat. Med., 1997), Iwahori et al. (Nat. Med., 6/1999), Lee et al. (Korean J. Pharm., 3/1999 EMBASE Abstract), Taniguchi et al. (Nippon Suisan Gakkaishi-Bulletin: Abstract, 1992), Kamata et al. (JP 56148245, JPAB Abstract), Itatani et al. (JP 46006373, CAPLUS Abstract), Narisu Keshhin KK (JP 07278003, WPIDS Abstract), or Nakamura (JP 57033579, JPAB Abstract).

Each of the cited references teach aqueous, methanolic, and/or other organic solvent extract material obtained from *Ecklonia cava* (also known as *Ecklonia cave* and kajime) - see entire documents.

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Again, please note that the recited compound (within an extract/extract material) would inherently and necessarily be present within the extract preparations taught by the cited references because, as readily admitted by applicants, the recited chemical compound is extractable using water as well as various other organic solvents such as ethanol and methanol, to name a few (see, e.g., paragraph bridging pages 7-8 of the instant specification). Accordingly, the claimed compound would inherently be present in the reference extract preparations.

Therefore, each of the cited references is deemed to anticipate the instant claims above, as drafted.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please note that the prior art references relied upon above and cited in the attached PTO-892 (Notice of References Cited) have not been provided with this Office action because these references were already provided to Applicants in the May 2001 Office action of co-related Application No. 09/629,342.

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In addition, clarification concerning the following matter is requested. It would appear that JP Patent No. 2001302655 (copy enclosed) is drawn to the same subject matter as instantly claimed and based upon similarities between the names of the inventors on the JP patent vs. the instant Application, that the instant inventors may be the same as those listed on the JP Patent, however the inventor names thereon are spelled differently (see enclosed JP Patent including the JPAB English overview which recites the English translation of the inventor's names). If the instant inventors are indeed the same as those recited on the JP Patent, it is requested the correct spelling for each of the instant inventors be provided in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654